

INTERVIEW SUMMARY

Examiner Aeder and Applicants' representative Mary Ann Brow conducted a telephonic interview on June 9, 2011. Claim 1 was discussed. In particular, Amendment of Claim 1 to remove the term "unfractionated" was discussed as a means of addressing the new matter rejection. Applicants also proposed the amendment of Claim 1 to recite that the heterogeneous DNA contains human DNA and other DNA. No agreement was reached.

REMARKS

Applicants note with appreciation that all prior rejections have been withdrawn. In the Office Action mailed March 23, 2011, the Examiner made a new rejection, rejecting Claims 1, 4-8, 11, 14, 19-21, 24, 28-30, and 35-40 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that "unfractionated" DNA is not found in the specification.

For business reasons and without acquiescing to the Examiner's arguments, and reserving the right to prosecute the original or similar claims in one or more future applications, the Claims 1, 14, and 24 are amended herein to delete the term "unfractionated." The claims are further amended to recite that "said heterogeneous DNA comprises human DNA that has not been specifically isolated from other DNA in said supernatant." This amendment to the claims finds support in the specification, *e.g.*, in Examples 1 and 2. In particular, paragraph [0059] describes the preparation of DNA from supernatant that was produced by centrifugation of a homogenate of stool sample and buffer. The DNA in the supernatant was prepared by standard techniques and was used in quantitative PCR (paragraph [0060]). For additional testing as described in Example 2, the samples are prepared as described as in Example 1, then further processed by sequence-specific hybrid capture of the human DNA (paragraph [0067]) prior to amplification. Thus, the isolated DNA of Example 2 is specifically isolated from other

DNA in the supernatant, in contrast to the DNA prepared in Example 1, in which the human DNA is not specifically isolated from other DNA in the supernatant.

It is well known in the art that stool samples contain a mixture of human DNA and other, nonhuman DNA. In DNA purified from stool samples, the human DNA typically represents less than about 5% - of the total DNA. See, *e.g.*, Jin, *et al*, Molecular approaches for colorectal cancer screening, European Journal of Gastroenterology & Hepatology 10:213-217(1996), at page 214, col. 2 (provided herewith). Thus, one of skill in the art would appreciate that the DNA prepared as described in Example 1, such that the human DNA is not specifically isolated from other DNA purified from the supernatant, contains both human DNA and other, non-human DNA.

Applicants respectfully submit that the claims as amended do not contain new matter and that they satisfy the requirements of 5 U.S.C. 112, first paragraph.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all grounds for rejection have been addressed and Applicants' claims should be passed to allowance. If the Examiner wishes to discuss this case, Applicants encourage the Examiner to call the undersigned at 608-662-1277 at the Examiner's convenience.

Dated: June 24, 2011

/Mary Ann D. Brow/

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